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| APPLICATION NO.                                   | VIERMATION NO. |  |  |
|---|----------------|--|--|
| 09/728,616  | 5191           |  |  |
| •   |                |  |  |
| Cooper & Dunham LLP                               |                |  |  |
| 1185 Avenue of the Americas<br>New York, NY 10036 |                |  |  |
|   | APER NUMBER    |  |  |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| ů.  | Application N .            | Applicant(s)  |  |  |
|---|----------------------------|---|--|--|
|   | 09/728,616                 | CASTELHANO ET AL.   |  |  |
| Office Action Summary   | Examiner                   | Art Unit  |  |  |
|   | La Tonia M. Fisher         | 1623  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period f r Reply  |                            |   |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any  Status |                            |   |  |  |
| 1) Responsive to communication(s) filed on  | ·                          |   |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ Th  | nis action is non-final.   |   |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims   |                            |   |  |  |
| 4) Claim(s) <u>1-7,12-14,16,17,19,21,24,25,28,30,3</u>  | 32,35,38,39,49,51,59 and 7 | 75 is/are pending in the application.                               |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |                            |   |  |  |
| 5) Claim(s) is/are allowed.   |                            |   |  |  |
| 6)☐ Claim(s) is/are rejected.   |                            |   |  |  |
| 7) Claim(s) is/are objected to.   |                            |   |  |  |
| 8) Claim(s) <u>1-7,12-14,16-17,19,21,24-25,28, 30, 32, 35, 38-39, 49, 51, 59 and 75</u> are subject to restriction and/or election requirement.   |                            |   |  |  |
| Application Papers  |                            |   |  |  |
| 9) The specification is objected to by the Examiner.  |                            |   |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |                            |   |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                            |   |  |  |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.   |                            |   |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |                            |   |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |                            |   |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |                            |   |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |                            |   |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |                            |   |  |  |
| <ol> <li>Certified copies of the priority documents have been received.</li> </ol>  |                            |   |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |                            |   |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |                            |   |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |                            |   |  |  |
| a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  |                            |   |  |  |
| Attachment(s)   |                            |   |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)   | 5) Notice of In            | ummary (PTO-413) Paper No(s)<br>formal Patent Application (PTO-152) |  |  |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 12-14, 16-17, 19, 21, 38 and 75 are drawn to 7-deaza-2-benzyl substituted purine compounds and a method for making same, classified in class 544, subclass 264+.
- II. Claims 24, 25, 28, 30, 32 and 35 are drawn to 7-deaza-2-benzyl-6-heterocyclic substituted purine compounds, classified in class 544, subclass 284.
- III. Claims 39 and 49 are drawn to a method for treating a disease associated with an A<sub>3</sub> adenosine receptor in a subject (patient or cell), classified in class 514, subclasses 261 and 266.
- IV. Claim 51 is drawn to a method for treating gastrointestinal disorder by administering a compound of Invention I or II, classified in class 514, subclass 266.
- V. Claim 59 is drawn to a method for treating eye damage by administering a compound of Invention I or II, classified in class 514, subclass 266.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions I and II identify two distinct compositions of matter. Invention II contains an additional heterogroup. Applicant is entitled to only one independent and distinct composition of matter. Additionally, the process in Invention I will not produce the compounds of Invention II.

Inventions I and III, IV and V are related as product and process of use. Likewise,
Inventions II and III, IV and V are related as product and process of use. The inventions can be

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shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of Invention I and Invention II may be used in materially different methods than those of Inventions III, IV and V.

Inventions III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions III, IV and V possess different functions. While the function of Invention III is to treat diseases associated with A3 adenosine receptor cells, the functions of Inventions IV and V, as claimed, are not limited to treatment of diseases associated with A3 adenosine receptor cells. Specifically, the functions of Inventions IV and V are treating of gastrointestinal disorder and damage to the eye, respectively, neither of which need not to be A3 adenosine related. Additionally, the Inventions produce different effects. Treating of the eye and a gastrointestinal disorder, either of which may or may not be A3 adenosine related, indicates that the Inventions produce different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their classifications and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is entitled to one

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composition of matter and one method for using same. A method will be examined insofar as it

relates to the elected composition of matter.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR

1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to La Tonia M. Fisher whose telephone number is (703) 306-5819.

The examiner can normally be reached on Monday - Friday from 9:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, James O. Wilson can be reached on (703) 308-4532. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4556 for regular

communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is (703) 308-1235.

**LMF** 

September 24, 2002

JAMES O. WILSON

SUPERVISORY PATENT EXAMINER

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